

Food and Drug Administration, HHS

§ 207.25

additional listing information requirements in § 207.31 remain applicable.

[45 FR 38043, June 6, 1980, as amended at 45 FR 32293, May 16, 1980; 52 FR 2682, Jan. 26, 1987; 55 FR 11576, Mar. 29, 1990; 64 FR 400, Jan. 5, 1999; 64 FR 56448, Oct. 20, 1999; 64 FR 63203, Nov. 19, 1999; 66 FR 5466, Jan. 19, 2001; 66 FR 59157, Nov. 27, 2001; 66 FR 5447, Jan. 19, 2001]

§ 207.21 Times for registration and drug listing.

(a) The owner or operator of an establishment entering into the manufacture or processing of a drug or drugs shall register the establishment within 5 days after the beginning of the operation and shall submit a list of every drug in commercial distribution at that time. If the owner or operator of the establishment has not previously entered into such an operation, the owner or operator shall register within 5 days after submitting a new drug application, abbreviated new drug application, new animal drug application, abbreviated new animal drug application, medicated feed mill license application, or a biologics license application. Owners or operators shall renew their registration information annually.

The schedule is as follows:

| First letter of company name | Date FDA will mail forms |
|------------------------------|--------------------------|
| A or B | January |
| C, D, or E | February |
| F, G, or H | March |
| I, J, K, L, or M | April |
| N, O, P, Q, or R | May |
| S or T | June |
| U, V, W, X, Y, or Z | July |

(b) Owners and operators of all registered establishments shall update their drug listing information every June and December.

[45 FR 38043, June 6, 1980, as amended at 55 FR 11576, Mar. 29, 1990; 64 FR 400, Jan. 5, 1999; 64 FR 56448, Oct. 20, 1999; 64 FR 63203, Nov. 19, 1999; 66 FR 59157, Nov. 27, 2001]

§ 207.22 How and where to register and list drugs.

(a) An establishment shall register the first time on Form FDA-2656 (Registration of Drug Establishment), obtainable on request from the Drug Listing Branch (HFD-334), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857, or from FDA district offices. An establishment whose drug registration for that year was validated under § 207.35 shall make subsequent annual registration on Form FDA-2656 as described in § 207.21(a) by mailing the completed form to the above address within 30 days after receipt from FDA.

(b) The first list of drugs and later June and December updates shall be on Form FDA-2657 (Drug Product Listing), obtainable upon request as described in paragraph (a) of this section. An establishment may submit, in lieu of Form FDA-2657, tapes for computer inputs containing the information specified in Form FDA-2657 if formats proposed for this use were reviewed and approved by the Drug Listing Branch (HFD-334), Center for Drug Evaluation and Research, FDA.

[45 FR 38043, June 6, 1980, as amended at 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990]

§ 207.25 Information required in registration and drug listing.

(a) Form FDA-2656 (Registration of Drug Establishment) provides for furnishing or confirming information required by the act. This information includes, for each establishment, the name and full address of the drug establishment; all trade names used by the establishment; the kind of ownership or operation (that is, individually owned, partnership or corporation); and the name of the owner or operator of the establishment. The term *name of the owner or operator* includes in the case of a partnership the name of each partner, and in the case of a corporation the name and title of each corporate officer and director and the name of the State of incorporation.

(b) Form FDA-2657 (Drug Product Listing) provides that information required by the act be furnished as follows:

(1) A list of drugs, including bulk drug substances and Type A articles for use in the manufacture of animal feeds as well as finished dosage forms, by established name and by proprietary name, that are being manufactured or processed for commercial distribution and that have not been included in any list previously submitted to FDA on